A. Engagements, you mean consulting projects? 03:30
Q. Uh-huh. 03:30
A. One for sure. It's still ongoing. And I may have had one other just briefly. 03:30
Q. Any of them as big as this one? 03:30
A. And when you say "big," what do you mean by big? 03:30
Q. Well $140,000, that's a reasonable amount of revenue wouldn't you say? 03:30
A. It is. 03:30
Q. I mean even at 550 an hour, that's 700 hours; right? No, that's wrong. 03:30
A. I can tell you this. I've been fully engaged with a client since June. 03:31
Q. In addition to this engagement? 03:31
A. Yes. This is on the side. 03:31
Q. Oh, this is on the side? 03:31
A. Prior to -- it started prior to and then this -- this has been done on weekends. 03:31
Q. Okay. 03:31
A. I do anything about 60 to 90 hours a week at that current client site. I have been since June. 03:31
Q. Okay. Will you pick up Exhibit 109? 03:31

A. Sure, if I can find it. Which one is that, sir? 03:31

Q. It's one of the sets of notes that you produced that we took last time. 03:31

A. Yes, got it. 03:32

Q. I'm looking at the first page of 109. Are you with me? 03:32

A. I am. 03:32

Q. Roman numeral I -- on 109, the first page is as I read the heading, "Collective Proof of Adulterated Digitek Making it to Market." 03:32

A. Yes. 03:32

Q. The first item Roman numeral I is Adverse Event Reports; right? 03:32

A. Yes. 03:32

Q. You are not a pharmacovigilence expert, are you? 03:32

A. I am not. 03:32

Q. You don't know -- you're not able to give any expert opinion about the reliability of the facts and circumstances in adverse event reports, are you? 03:32

A. No, this was based on observation that was in one of the EIRs. I'd have to look. 03:33

Q. Okay. What you mean by that? 03:33

A. There was a -- in reviewing, if I'm not mistaken an EIR or 483, that this is one of the items the agency found specifically. 03:33

There was a death within a certain period of time or whatever, so... 03:33

Q. That was the report? 03:33

A. Yes. 03:33

Q. That wasn't a finding of the EIR. 03:33

A. It was a report. 03:33

Q. Yeah. 03:33

A. That there was a death from an adverse event and it was not reported to the FDA. 03:33

Q. So agency, to be clear -- 03:33

A. Uh-huh. 03:33

Q. -- the agency, the FDA didn't find that there was a death within several hours of taking the product. 03:33

A. They found there was an adverse event that had not been reported to them that stated that there was a death within a certain short period of time, yeah. 03:33

Q. And, again, you're not qualified to assess the reliability of the facts and circumstances that are set forth in or were set forth in that adverse event, are you? 03:33

A. No, but it triggered my eye because it was a short period of time for an immediate dose of product, and it was like maybe there's something. That was actually the first thing that got me started on this -- this review. 03:34

Q. Well, Dr. Bliesner, I'm a little bit confused. 03:34

A. Uh-huh. 03:34

Q. You say -- when you make that statement -- 03:34

A. Uh-huh. 03:34

Q. -- you're presuming the accuracy or -- I'm sorry. You're presuming the cause and effect relationship between taking a product and the event set forth in the adverse event report, aren't you? 03:34

A. Say that again specifically. 03:34

MR. ANDERTON: Phil, would you please read that back? 03:35

(Whereupon, the testimony was read back by the court reporter, as recorded above) 03:35

THE WITNESS: There is a potential cause and effect there. 03:35

BY MR. ANDERTON: 03:35

Q. Potential? 03:35

A. Yes. 03:35
Q. Which you've said you're not qualified 03:35
to evaluate. 03:35
A. No, that's correct. 03:35
Q. Okay. 03:35
A. But the potential was there, which 03:35
from -- would you like me to continue or stop? I 03:35
don't want to... 03:35
Q. You were answering. 03:35
A. Okay. From a, you know, compliance 03:35
standpoint, you look at that and you say to 03:35
yourself, jeez, if there was an adverse event, a 03:35
person potentially passed away in two and a half 03:35
hours, you sit back and go okay, from a product 03:35
standpoint, me working for this company again, 03:35
from a product standpoint, jeez, could that have 03:35
been product-related? 03:35
So you go look and you see it's immediate 03:35
dosage form, and you try to pull up the PK lead 03:35
out of an ANDA. And if the PK says it's like six 03:35
hours or whatever, you don't worry about it. You 03:35
move on. It's not related to that. That's how 03:35
the logic went on that. 03:35
Q. Okay. And so is that proof that 03:35
adulterated Digitek made it to market? 03:35

A. No, it's not proof. 03:35
Q. Okay. You characterize it as such in 03:35
this document. That's just why I'm -- 03:36
A. My notes -- 03:36
Q. Okay. 03:36
A. Proof is -- 03:36
Q. So it's not proof? 03:36
A. No, it's not. It's a piece of data that 03:36
was the start of a potential pattern that was the 03:36
first thing -- quite honestly that was first thing 03:36
that caught my eye so I just started digging. 03:36
Q. I'm merely asking about your 03:36
characterization in your document. 03:36
A. Yes. 03:36
Q. So it's not proof. 03:36
A. No. 03:36
Q. And look at Roman numeral VI. 03:36
A. Okay. 03:36
Q. Company internal documents and 03:36
investigations. 03:36
A. Uh-huh. 03:36
Q. You see your reference to purchase 03:36
presses. 03:36
A. Yes. 03:36
Q. How is that proof that adulterated 03:36

Digitek made it to market? 03:36

A. There were a couple of circumstances as 03:36

I recall where they had reasonable suspect that 03:36

they had problems with tablet presses. So they 03:37

committed -- if I'm not mistaken without taking 03:37

more time and going back and looking at the 03:37

document -- they would purchase new presses with 03:37

weight controls or whatever and they never did. 03:37

And that happened over the course of a -- if I'm 03:37

not mistaken, going back to look at the book, a 03:37

year or two. 03:37

Q. Okay. So you work with companies all 03:37

the time on GMP compliance; right? 03:37

A. That's correct. 03:37

Q. And one of the things I'm sure you tell 03:37

them is that they ought to be constantly 03:37

evaluating and reevaluating their quality systems; 03:37

right? 03:37

A. Absolutely. CGMP current today, not 03:37

yesterday. 03:37

Q. Exactly. And so it's an evolutionary 03:37

process. 03:37

A. Absolutely. 03:37

Q. Never stops evolving. 03:37

A. No, it doesn't. 03:37

Q. So upgrading presses or purchasing new presses -- 03:37

A. Uh-huh. 03:37

Q. -- doesn't say anything about whether adulterated product was produced or made it to market, does it? 03:37

A. It doesn't say anything about whether adulterated products have made it to the market. 03:38

Q. That's right. 03:38

A. I wouldn't agree with that statement. It -- it shows they had problems. 03:38

Q. It does? 03:38

A. It shows they had problems with the presses because they said they had problems with the presses. 03:38

Q. They didn't say they had problems. They said they wanted to purchase new presses 03:38

A. With weight control, if I remember correctly. 03:38

Q. Okay. So that doesn't mean they're having problems; it means they're looking at a different technology. 03:38

A. Uh-huh. 03:38

Q. Right? 03:38

A. Yes, an upgrade if you will. 03:38

Q. Well, let's call it an upgrade. 03:38
A. Uh-huh. 03:38
Q. Doesn't mean you had problems before; 03:38
right? 03:38
A. But they committed to the FDA and they 03:38
didn't purchase them, as I recall. 03:38
Q. You just changed the subject, 03:38
Dr. Bliesner. 03:38
A. I did? 03:38
Q. Yeah? 03:38
A. I'm sorry. 03:38
Q. I asked you if the mere act of upgrading 03:38
presses means that they had problems. 03:38
A. Not specifically, no. 03:39
Q. And so purchasing presses doesn't 03:39
constitute proof that there is adulterated Digitek 03:39
in the market, does it? 03:39
A. Not necessarily, no. 03:39
Q. But you characterize it on that 03:39
document. 03:39
A. It's my notes, uh-huh. 03:39
Q. You understand, Dr. Bliesner? 03:39
A. I do sir. 03:39
Q. That we get these documents. 03:39
A. Uh-huh. 03:39

Q. And we get your report? 03:39
A. Uh-huh. 03:39
Q. And we are -- we have to try to figure 03:39
out -- 03:39
A. Uh-huh. 03:39
Q. -- how you reached the conclusions that 03:39
you reached. 03:39
A. Correct. 03:39
Q. That's what we're doing today. 03:39
A. I understand. 03:39
Q. So I understand that this is your notes. 03:39
A. Uh-huh. 03:39
Q. You're the one who characterized this as 03:39
proof -- 03:39
A. Uh-huh. 03:39
Q. -- that adulterated Digitek was in the 03:39
market. 03:39
A. Uh-huh. 03:39
Q. I'm just inquiring about some of these 03:39
things. 03:39
A. Understood. 03:39
Q. Excuse me? 03:40
A. Uh-huh. 03:40
Q. Dr. Bliesner, would you now find Exhibit 03:40
107. It's another set of notes that we collected 03:40

from you last time. 03:40
A. May I see the top of? 03:40
Q. You may. It the thicker one. It's the 03:40
Mylan deposition exhibits. 03:40
A. I have it here. 03:40
Q. Okay. You see on the first page there 03:40
it says probably equals more likely than not? 03:40
A. Uh-huh. 03:40
Q. When did you write that? 03:40
A. I don't recall specifically, but I'm -- 03:40
my suspect is it was the preparation meeting 03:40
before the first deposition. 03:40
Q. Okay. And -- 03:40
A. Because I was still struggling with that 03:40
whole concept of possible and probable. 03:40
Q. Well, you understand what probably 03:41
meant; right? 03:41
A. If I'm not mistaken I was told that's 03:41
what it was. It was a definition. These were 03:41
my -- my documents that I had laid out as an 03:41
indices in the discussion, and it was the first 03:41
thing I wrote on, so... 03:41
Q. Okay. So you wrote in your discussions 03:41
with Plaintiffs' counsel, that probably equals 03:41
more likely than not; right? 03:41

A. I'm fairly confident that's what they mentioned to me as the definition. 03:41

Q. Okay. And the very next day -- 03:41

A. Uh-huh 03:41

Q. -- you testified that you did not know the difference between possibility and probability? 03:41

A. Obviously I was still confused with that. 03:41

Q. And in the same meeting where you wrote probably equals more likely than not -- well, strike that. 03:41

A. I -- 03:41

Q. Strike that. 03:41

A. Okay, okay. 03:41

Q. Look at the second page of Exhibit 107, please. 03:41

A. Sure. 03:41

Q. You made a note about Exhibit M09? 03:42

A. Yes. 03:42

Q. You see that? 03:42

A. Yes. 03:42

Q. And you indicated outside of spec 98 to 103 percent. And then you parenthetically indicated 97.1 percent. 03:42

Do you see that? 03:42
A. I do. 03:42
Q. 97.1 is well within specification for 03:42
Digitek as approved by the FDA in the ANDA, isn't 03:42
it? 03:42
A. I don't know. I'd have to go back and 03:42
look at it. 03:42
Q. Well, didn't you -- I mean if you made a 03:42
note that something was out of spec. 03:42
A. Somebody made a statement somewhere in 03:42
this document whatever M09 was apparently. I'm 03:42
not going back and looking at it. 03:42
Q. I understand. 03:42
A. That somebody made a statement you 03:42
realize that what this is, is not a detailed 03:42
reading of these documents because the search 03:42
capabilities of that Crivella West I think is the 03:42
name of it, is abysmal, so you can't find 03:43
anything. So I just basically went in and said, 03:43
pulled up 01, skimmed it. If I saw something, you 03:43
know -- well, I tried to do a thumbnail summary on 03:43
there so later on if I needed to go pull it up, I 03:43
would. So -- 03:43
Q. Okay. 03:43
A. Obviously -- or maybe not obviously -- 03:43

it looks as if I probably printed that one and it's somewhere in the stack. 03:43

Q. And you acknowledge of course that -- that the fact that it might -- that UDL might have or Mylan might have a tighter specification says nothing about whether the product is actually out of specification; correct? 03:43

A. That's correct. 03:43

Q. At the end of the day, the operative number with respect to whether something is in or out of specification is the number the number for any particular attribute set forth in the ANDA; is that right? 03:43

A. The approved application; that's correct. 03:44

Q. Okay. So if you make a product and it's distributed by somebody else and they, the distributor prefers tighter specifications, that doesn't have any bearing on whether the product you make is actually out of specification, does it? 03:44

A. Tighter specs are always around. 03:44

Q. Okay. 03:44

A. It's an additional level of control. 03:44

Q. And if they had tighter specs and the 03:44

product doesn't meet them but still falls within the ANDA specifications, that product is within specification; right? 03:44

A. For the manufacturing service. 03:44

Q. Yes. 03:44

A. In this particular case. UDL probably would have rejected it because that's their spec. 03:44

Q. Fair enough, but with respect to that -- 03:44

A. The original ap., yes. 03:44

Q. And with respect to whether it is out of spec, out of specification in the eyes of the FDA, it is not out of specification; correct? 03:44

A. I would say that's a fair statement, yes. 03:44

Q. Okay. Can you look at the page that refers to Exhibit M44, please? 03:45

A. Sure, yes. 03:45

Q. Did you -- do you recall enough about M44 from looking at this document to know whether you read it or not? 03:45

A. I don't. 03:46

Q. Okay. Your thumbnail sketch as you described it indicates this is an e-mail from Sue Powers to Chuck Kuhn, regarding the recall costs for UDL. 03:46

Do you see that? 03:46
A. I do. 03:46
Q. You wrote that; right? 03:46
A. Yes. 03:46
Q. All right. So that's some brief 03:46
characterization of what you saw when you read 03:46
that document? 03:46
A. I scanned it. I didn't read it, I 03:46
scanned it. 03:46
Q. Do the costs of a recall have anything 03:46
to do with whether there's adulterated or out of 03:46
specification product in the market? 03:46
A. I don't believe so. 03:46
Q. Look at the page of Exhibit 107 that 03:46
refers to M56, please. 03:47
A. 56? 03:47
Q. Yes, please. 03:47
A. Uh-huh. 03:47
Q. Do you see your handwritten note about 03:47
that? 03:47
A. I do. 03:47
Q. And it says that UDL to file from Lee 03:47
Roedke, 16 September, 2006, Activis warning 03:47
letter, Little Falls, New Jersey. Did I read that 03:47
correctly so far? 03:47

A. What did you say? 03:47
Q. UDL to file from Lee Roedke, 16 03:47
September, abbreviated, 2006? 03:47
A. Uh-huh. 03:47
Q. Activis warning letter, Little Falls, 03:47
New Jersey. Did I read that correctly so far? 03:47
A. Yes. 03:47
Q. It goes on to say not addressing FDA ADE 03:47
concerns. Did I read that correctly? 03:47
A. Yes. 03:47
Q. And ADE concerns in that context is an 03:47
acronym for adverse drug events; correct? 03:48
A. Without specifically pulling it up, I 03:48
would say yes, that's true. 03:48
Q. Okay. Do you use ADE for any other 03:48
purpose in the context of performing your GMP 03:48
compliance consulting services? 03:48
A. No. But like you said, I'm not an 03:48
adverse drug event person. 03:48
Q. This is your terminology. 03:48
A. This is a summary. 03:48
Q. I understand. 03:48
A. And, again, unless we pull it up, that 03:48
may be what they refer to it as in the e-mail. 03:48
Chances are that's what it is. 03:48

Q. But you made the note. 03:48
A. Yes. 03:48
Q. Do you mean to use the term ADE to stand for adverse drug event? 03:48
A. More than likely, yes. 03:48
Q. Okay. 03:48
A. Uh-huh. 03:48
Q. I'm handing you, Dr. Bliesner, a document that has been marked as Defendant's Exhibit 87. 03:48
A. Okay. 03:48
Q. Take a moment please and review that document very briefly. 03:48
A. Uh-huh. 03:48
Q. Let me know when you have reviewed it. 03:48
A. Sure. Okay. 03:49
Q. Have you seen that document before? 03:49
A. I'm not sure. 03:49
Q. All right. Well you see that -- that it is referencing a warning letter -- 03:49
A. Uh-huh. 03:49
Q. -- issued to Activis in August of 2006. 03:49
A. Uh-huh. 03:49
Q. That relates to adverse drug experiences. Do you see that? 03:50

A. I do. 03:50

Q. And this is the warning letter that you referred to earlier when you were talking about the reports and the ADE, and we talked for a moment about the connection, whether there's reliability in ADE reporting, and all that. It's the same point. 03:50

A. I'll take your word. 03:50

Q. So in this letter, the FDA accepts the corrective actions Activis has proposed and implemented with respect to that warning letter; right? 03:50

A. Correct. 03:50

Q. Okay. So when you wrote in response to or in connection with Exhibit M56 that Activis wasn't addressing the ADE concerns, is that accurate? 03:50

A. It's what's in the e-mail more than likely -- or memo, whatever it is. 03:50

Q. Okay. 03:50

A. It's somebody, whoever that individual was. 03:50

Q. Lee Roedke. 03:50

A. Apparently that's who it was. Again this is a snapshot summary, glancing it at this. 03:50

Whether it's an e-mail, memo or whatever. 03:51
Q. Okay. 03:51
A. That's their concern I'm assuming, not 03:51
going back and pulling it out. 03:51
Q. Okay. Well -- 03:51
A. Knee deep in paper. 03:51
Q. Yeah. Unfortunately that's a necessary 03:51
part of this process, Dr. Bliesner. All right. 03:51
Find 108, please. 03:51
A. Which one are we on, sir? 03:51
Q. Exhibit 108. 03:51
A. Exhibit 108. Yes, sir. 03:51
Q. What do you mean when you use the term 03:52
"blend uniformity failure." To you, what does 03:52
that mean? 03:52
A. Blend uniformity failure? 03:52
Q. Yeah. 03:52
A. It means that blend gets sampled and 03:52
tested wouldn't necessarily, does not have the, 03:52
you know, assay value that it was supposed to 03:52
have. 03:52
Q. At what point of the sampling and 03:52
testing process does something become a blend 03:52
uniformity failure? 03:52
A. Well, there's a spec for blend 03:52

uniformity test. 03:52

Q. So by that you mean that you take a sample of the blend, you conduct a chemical test on it to determine the assay of that sample, and then you apply the specifications to determine whether that sample -- whether the assay value for that sample is within those specifications; correct? 03:52 03:52 03:53 03:53 03:53 03:53 03:53

A. That's a fair assessment. 03:53

Q. And so when you sample blends for testing to determine whether it is uniformly distributed -- excuse me -- most manufacturers take samples of blend in duplicate or triplicate; correct? 03:53 03:53 03:53 03:53 03:53 03:53 03:53

A. Most manufacturers? I don't know if I can speak to most manufacturers, but there's more than one. 03:53 03:53 03:53

Q. Okay. So it's not uncommon for a pharmaceutical manufacturer to take blend samples in duplicate or triplicate; right? 03:53 03:53 03:53

A. I would say that's fair. 03:53

Q. And that is an acceptable practice so long as you, the manufacturer, have an appropriately drafted SOP? 03:53 03:54 03:54

A. Manufacturer, during process validation 03:54

will come up with a sampling plan, and a sampling approach. Manufacturing does the sampling and delivers the sample for you. 03:54

Q. So it is acceptable to draft a sampling plan with respect to blend sampling that calls for blend samples to be taken in duplicate or triplicate; right? 03:54

A. At least, yes. 03:54

Q. And it is acceptable to draft a testing plan. 03:54

A. Yes. 03:54

Q. For blend samples that allows for testing the second or third sample from a given location under appropriate circumstances; right? 03:54

A. Content uniformity, yeah, under appropriate circumstances. 03:54

Q. Well, so -- so it is -- you've seen and it is okay to have a sampling plan that says you take blend samples in triplicate, for example. 03:55

A. Uh-huh. 03:55

Q. You test the first sample from each location and in appropriate circumstances if -- if one of those samples is not tested within specification, you may test the second sample from that location. 03:55

A. Same location. I would say it's a fair statement if it's in the protocol. 03:55

Q. If it's in the protocol. 03:55

A. Yes. 03:55

Q. And you have to have the circumstances that are called for by the protocol and that allow you to test that second sample; right? 03:55

A. Yes 03:55

Q. And you have to do an appropriate inspection or investigation and try to determine why the first sample tested out of specification; correct? 03:55

A. Correct. Just for content uniformity for finished products, yes. 03:56

Q. If you have an initial sample of the triplicate sample that tests out of specification, do you call that a blend failure? 03:56

A. Do you want to say that again? 03:56

MR. ANDERTON: Phil, would you read it back? 03:56

(Whereupon, the testimony was read back by the court reporter, as recorded above) 03:56

THE WITNESS: Potentially. 03:56

BY MR. ANDERTON: 03:56

Q. Potentially. 03:56

A. Yes. 03:56

Q. But if you have a protocol that allows you to test the second or third sample after conducting an appropriate investigation and after following the protocol properly -- 03:56

A. Uh-huh. 03:56

Q. -- that first out of specification result is not a blend failure, am I correct? 03:56

A. If it meets the protocol, that is correct. 03:56

Q. Okay. So you wouldn't call it a blend failure until you've run all the way to the end of the protocol -- 03:57

A. Huh-huh. 03:57

Q. -- is the way I'll describe that to you; is that correct? 03:57

A. That's a fair way to put it. 03:57

Q. Okay. Which might mean in certain circumstances until you've tested the third of the triplicate samples from one or more locations; right? 03:57

A. Yes. 03:57

Q. When you use the term -- and looking at Exhibit 108. 03:57

A. Yes. 03:57

Q. Well, hold on one second. 03:57

MS. DREWES: I don't want to interrupt, 03:57
but on that hard drive that you -- that the 03:57
witness gave, is it okay with everyone if we 03:57
give everyone a CD attached with the documents 03:57
rather than a hard copy? Because apparently 03:57
you can't read them when they were printing. 03:57

MR. ANDERTON: Yeah, that's acceptable to 03:58
me. Mike, are you all right with that? 03:58

MR. KERENSKY: Your voice was too faint 03:58
for to me to hear your comment, ma'am. 03:58

MS. DREWES: Would the hard drive that 03:58
Dr. Bliesner gave us earlier, today, the -- we 03:58
can print the -- we can print the documents 03:58
but they are not legible, some of them, when 03:58
we print them. For some reason they come out 03:58
really dark is what I'm told. 03:58

So if we can just give everyone a disc if 03:58
that's agreeable to you. 03:58

MR. ANDERTON: Are you okay with that, 03:58
Mike? 03:58

MS. DREWES: Apparently you can read it 03:58
on the disc or on the computer screen. 03:58

MR. KERENSKY: Just as long as a general, 03:58
average, normal, everyday computer will open 03:58

it, I'm happy. 03:58

MR. ANDERTON: Well, that's just 03:58

described my unit, so. 03:58

BY MR. ANDERTON: 03:58

Q. And then Dr. Bliesner, continuing on 03:58

with this line of questioning, if you -- again if 03:58

your protocol is appropriately drafted and you 03:59

follow that factual progression that I just 03:59

described, where you take samples of a blend and 03:59

you test the first sample from a location and it 03:59

is out of specification, then you follow the 03:59

protocol and that results in you testing then the 03:59

second sample from that location and it is within 03:59

specification, it's okay to release that batch; 03:59

right? 03:59

A. If you're meeting your protocol. 03:59

Q. If you have a protocol that allows for 03:59

all of that, specifies it, and if you comply with 03:59

it along the way; correct? 03:59

A. That's a reasonable statement. 03:59

Q. It's okay to release that batch? 03:59

A. That blend, sure. 03:59

Q. That -- 03:59

A. Final blend in this case. 03:59

Q. That initial I guess then -- correct. 03:59

So let me ask it another way. 03:59
That initial out-of-specification result 04:00
doesn't require that the entire blend and 04:00
therefore the entire batch be rejected. 04:00
A. Not necessarily. 04:00
Q. Okay. 04:00
A. It may be, you know, extraordinary 04:00
circumstances where it comes in at 25 percent of 04:00
assay or whatever, then it's a whole different 04:00
bailiwick. 04:00
Q. Then your -- well, then your 04:00
investigation your protocol provides for probably 04:00
is going to reveal something other than just a 04:00
single out-of-specification result? 04:00
A. More than likely, yes. 04:00
Q. Okay. 04:00
MR. KERENSKY: Are you guys still there? 04:00
MR. ANDERTON: Yeah, we are here. 04:00
MR. KERENSKY: Man, you got quiet. I 04:00
thought you hung up on me. 04:00
BY MR. ANDERTON: 04:00
Q. Dr. Bliesner, when you did your paper 04:00
audit of -- of this -- of Activis to prepare your 04:00
report -- paper audit is your term not mine -- did 04:01
you ask for and did you receive the SOP of Activis 04:01

Totowa that provides the protocol for testing blend samples and retesting second or third samples if you have an initial out-of-specification result? 04:01

A. I don't think I specifically asked for that SOP. I remember reviewing an investigation having to do with blend uniformity failure. 04:01

Q. If you didn't ask for it, does that mean you didn't review it either? 04:01

A. I don't know if I could say that. I'd have to go back and look at the paper at I reviewed. 04:01

Q. Okay. 04:01

A. With respect to that investigation. 04:01

Q. The documents -- well, the documents that you reviewed -- 04:01

A. Uh-huh. 04:02

Q. -- are set forth in your report; right? 04:02

A. They should be, yes. 04:02

Q. So if you reviewed it, our review of those documents will reveal that you reviewed it? 04:02

A. That I reviewed it, yes. 04:02

Q. Right. 04:02

A. That's a fair statement. 04:02

Q. So if it's not listed among the 04:02

documents that you reviewed -- if it's not listed in your report, it's not something you reviewed? 04:02

A. Not necessarily. 04:02

Q. Pardon? 04:02

A. They're not mutually exclusive, most of it because of all the volume of documents here. It obviously didn't include every single one that I reviewed, just ones that I felt had pertinent points with respect to this. 04:02

Q. If it's not listed in your report -- 04:02

A. Yes. 04:02

Q. -- is it fair to say that you didn't place any significance on it and didn't rely on it in drafting your report? 04:02

A. I didn't rely on it. I don't know if significance is a word that I would use. 04:02

Q. How are we to know or to identify if I asked you right now whether you reviewed this SOP -- 04:03

A. Uh-huh 04:03

Q. -- and it's not listed in your report -- 04:03

A. That's right. 04:03

Q. -- how would you know? 04:03

A. It's not listed in the report. I'd go through this index and see if I popped it up. 04:03

Q. And if it's not in this index? 04:03
A. And it's not in the supplemental 04:03
documents that were sent to me by -- then chances 04:03
are I didn't review it. 04:03
Q. Okay. 04:03
I'm going to hand you a document that has been 04:03
marked as -- well, what's it say on there? 04:03
A. 58. 04:03
Q. 58? 04:04
A. Yeah. 04:04
MR. ANDERTON: Plaintiffs' Exhibit 58. 04:04
Plaintiffs', Mike. 04:04
MR. KERENSKY: Got it. 04:04
BY MR. ANDERTON: 04:04
Q. Have you seen that before, Dr. Bliesner? 04:04
A. Isn't this one that we -- the 483s that 04:04
were included before? Can I take a look at the 04:04
report? I'm pretty sure that I have, but I just 04:04
want to make sure. 04:04
Q. Well, if you didn't look at this, you 04:04
don't have a report. 04:04
A. Okay. 04:04
Q. But you may do whatever you like to 04:04
satisfy yourself, but I guess I can shortcircuit 04:04
that. 04:04

A. Okay. Please. 04:04

Q. Well, I'm here to help, Dr. Bliesner. 04:04

Sarah will tell you I'm a giver. 04:05

MS. DREWES: Oh, yeah. Big time. 04:05

MR. KERENSKY: Note the snickers on the phone. 04:05

MR. ANDERTON: I'm sorry. Defense Exhibit 58, Mike. I misspoke earlier. 04:05

MR. KERENSKY: About you being a giving person? 04:05

MS. DREWES: Yeah, but got also about the exhibit. 04:05

MR. KERENSKY: That you are here to help? You're not with the IRS. 04:05

MR. ANDERTON: It's Defendant's Exhibit 58. 04:05

MR. KERENSKY: Thank you. 04:05

MR. ANDERTON: It's Plaintiffs' Exhibit 90, I believe. No. Not true. 04:05

BY MR. ANDERTON: 04:05

Q. Dr. Bliesner, did you review this or not. What do you think? 04:05

A. Yes. 04:09

Q. What page of your report are you looking at? 04:09

A. 47. 04:09
Q. What reference? 04:09
A. A37. 04:09
Q. Well? 04:09
A. By the look of it. 04:09
Q. That's an EIR, not a 483. 04:09
A. It is the EIR that had the 483s in them. I misspoke. I'm sorry. 04:09
Q. So you didn't review this apparently? 04:09
A. The 483s stand-alone? 04:09
Q. Yes. 04:09
A. No, it would be the EIR. 04:09
Q. So that's Exhibit 91. You agree with that; right? 04:09
A. Yes. 04:10
Q. All right. I'm going to hand you a copy of Exhibit 91. 04:10
A. Okay. 04:10
Q. So that we do this and keep you as comfortable as you need to be. I'm here for your comfort. 04:10
I would like you to first look at the document I just handed you and tell me if you reviewed that document. 04:10
A. 91. Plaintiffs' Exhibit 91, yes, sir. 04:10

Q. Okay. Turn to page 43 of that document. 04:10
A. May have a second, please? I want to 04:10
make sure that I -- because there were some of 04:10
these reports that didn't necessarily have all of 04:11
the pages that came with them, the EIR. There was 04:11
one circumstance that I recall that didn't. So I 04:11
want to make sure that what I've got over here is 04:11
the same and inclusive. 04:11
Q. Okay. 04:11
A. Okay. Is that fair? 04:11
Q. Well, I guess I would hope that you 04:11
would have noted in your report when you reviewed 04:11
a document that was incomplete, but you didn't do 04:11
that with respect to this document. 04:11
A. I just want to look at it. 04:11
Q. Of course you do. 04:11
THE VIDEOGRAPHER: While he's doing that, 04:11
you have five minutes left on the tape. 04:11
MR. ANDERTON: Let's go off the record 04:11
and change the tape. 04:11
THE WITNESS: The time is 4:13 p.m. 04:11
We're going off the record. 04:11
(Short break) 04:21
THE VIDEOGRAPHER: The time is 4:24 p.m. 04:21
We are on the record. This is the beginning 04:22

of tape eight. 04:22

BY MR. ANDERTON: 04:22

Q. Dr. Bliesner, are you all set? 04:22

A. Yes, sir. 04:22

Q. Okay. I want to ask you -- 04:22

Dr. Bliesner, I'm going to go away from that 04:23

document for just a moment and ask you a general 04:23

question. 04:23

A. Okay. 04:23

Q. You are a chemist by trade; right? 04:23

A. I am a Ph.D. and analytical chemist by 04:23

training. 04:23

Q. Does that mean the answer to my question 04:23

is yes? 04:23

A. Chemist? Yes. Sorry. There are many 04:23

flavors of chemists. That's why. 04:24

Q. I understand, but above all else as a 04:24

matter of fact you call yourself a chemist? 04:24

A. A research chemist, yes, I do. 04:24

Q. When testing a tablet and particularly a 04:24

solid oral dose tablet for potency -- 04:24

A. Uh-huh. 04:24

Q. -- what method would you use if you 04:24

could use any method you wanted? 04:24

A. Not to sound cryptic, but it depends on 04:24

the dosage form and what the characteristics are and what it's amenable to as far as analysis goes. 04:24

Q. What do you mean by that? 04:24

A. Well, it turns out that certain compounds might not be appropriately soluble let's say and therefore easily dissolved and injected into an HPLC system let's say. 04:24

Q. Did you review the ANDA for Digoxin and particularly for the Digitek version of Digoxin tablets manufactured by Amide and then Activis sufficiently to allow you to have an opinion about which methods could be used to examine the potency of a tablet -- of one of those tablets? 04:25

A. I'm sorry. Go again. 04:25

MR. ANDERTON: Phil, can you get that? I did it very methodically. I would like Dr. Bliesner to hear that. I think I got it right. 04:25

THE WITNESS: If I recall, I didn't get an opportunity to read all of the ANDA sections because I think that they were all available to me at the time of review. Just to put that in perspective. 04:26

As far as being able to assess whether -- 04:26

I guess the question is assess whether the methods are appropriate for use? 04:26

BY MR. ANDERTON: 04:26

Q. No. Do you have an opinion about -- about which of those -- which of the available methods to test a tablet for potency could be used? 04:26

A. Could be used with -- HPLC is a method of choice. 04:26

Q. Okay. 04:26

A. If I'm not mistaken, having looking at the 484 stuff, those were HPLC methods for assays and related compounds. 04:26

Q. And the Activis analytical method was also HPLC methods; correct? 04:26

A. I'm pretty sure yes, yes. 04:27

Q. So unless nobody knew what they were doing, HPLC was an acceptable method to test this compound; correct? 04:27

A. For assay. 04:27

Q. For assay. 04:27

A. Correct. 04:27

Q. Well, and to go back to the term I used, for potency. 04:27

A. Yes. Assay, potency, same thing. 04:27

Q. Okay. What about single point UV? How does that compare to HPLC as a test method to test the potency of a tablet and specifically of one of these Digitek Digoxin tablets? 04:27

A. Single point UV? 04:27

Q. Yes. 04:27

A. How would it compare? It depends because LC is a separations technique that separates out any potential interference from the main component so you get an assay. An HPLC system essentially a UV system at the end. The detector for HPLC is just a UV. But in this case it is has, if you will, as an analogy, the HPLC is a means of preparing the sample so you're looking at a single component when it goes into the UV detector; okay? If you have -- it is possible with a product to develop and validate a method, single point UV method if there are no interferences. 04:27 04:28 04:28 04:28 04:28 04:28 04:28 04:28

Q. If somebody sent you a sample -- 04:28

A. Uh-huh. 04:28

Q. -- and said Dr. Bliesner, chemist -- Ph.D. Chemist Bliesner, we'd like you to examine this tablet for potency. 04:28 04:28

A. Uh-huh. 04:28

Q. How would you compare the reliability of results of a test conducted using single point UV versus a test using HPLC? 04:28 04:28 04:29

A. How would you compare? 04:29

Q. How would you compare? Not literally how would you put them side by side and compare. How would you characterize the differences between results reached using single point UV versus the results reached using HPLC. Is one more reliable than the other? 04:29 04:29 04:29 04:29 04:29 04:29

A. Not necessarily. It depends on whether there are interference issues. You've got to realize that HPLC with a UV detector is a single point UV detection, just like you put it into a UV spectrometer. Same thing. It's only a single point. 04:29 04:29 04:29 04:29 04:29 04:29

Q. So you need to know more about the circumstances before you would be able to -- 04:29 04:29

A. Absolutely. Sure. 04:29

Q. Be able to compare the reliability of outcomes for -- 04:29 04:29

A. Right. 04:29

Q. -- those two tests. 04:29

A. For instance, they do dissolution testing. And the dissolution method is UV, but 04:29 04:29

there is a whole -- if I recall correctly, pulling off memory -- there is a derivatization and things that like that with respect to the UV because that would suggest that there are potential interferences. And derivatization and looking at it in the means that they did would suggest -- not having looked at the validation -- that they were able to get around interferences in that fashion. 04:29 04:30 04:30 04:30 04:30 04:30 04:30 04:30

Q. Just to be clear with respect to Activis, are the entirety of your opinions in this case set forth in the report you've issued? Do you have any supplemental or additional opinions with respect to Activis? 04:30 04:30 04:31 04:31 04:31

A. I don't believe so. 04:31

Q. Well, you don't believe so or you don't? 04:31

A. It's a broad statement. 04:31

Q. I need this question to be answered definitively, Dr. Bliesner. It's a very important question. 04:31 04:31 04:31

A. Additional, post-the-report? 04:31

Q. Yes. 04:31

A. In the report? 04:31

Q. Yeah, you have issued a report in this case -- 04:31 04:31

A. Yes. 04:31

Q. -- that we've been told contains your opinions -- 04:31

A. Yes. 04:31

Q. -- about Activis. And there was some exchange last time about whether you had an opinion about Mylan or didn't have an opinion and we got a representation from Plaintiffs' counsel about that, and that issue is done and resolved as far as we're concerned. 04:31

A. Okay. 04:31

Q. So I'm asking you now strictly about Activis and the opinions that are set forth in your June 15, 2010, report. 04:32

A. Yes. 04:32

Q. About Activis. 04:32

A. Yes. 04:32

Q. Do they -- do they comprise the entirety of your opinions about Activis in this case? 04:32

A. That's a fair statement, yes. 04:32

Q. Yes, they do? 04:32

A. Uh-huh. 04:32

Q. You need to say that. 04:32

A. Yes, they do. 04:32

Q. Okay. So there are no supplemental opinions about Activis that are not contained in 04:32

your report? 04:32
A. I've not reviewed any documentation or 04:32
anything else that would supplement what I've 04:32
written in the report. 04:32
Q. So again need this answered my way. You 04:32
don't have any supplemental opinions about Activis 04:32
that are not contained in this report; is that a 04:32
correct statement? 04:32
A. That is a correct statement. 04:33
Q. Thank you. 04:33
So the process -- well, you -- the product 04:33
that was in the market and subject to recall you 04:33
know was .125 and .25 milligram Digitek. You are 04:33
aware of that; right? 04:33
A. Yes, sir. 04:33
Q. Two dose strengths; right? 04:33
A. Yes, sir. 04:33
Q. And both processes were validated; 04:33
correct? 04:33
A. I have not seen the process validation 04:33
reports so I can't say definitively, but because 04:34
they're in the application and it was approved, 04:34
one would extrapolate that they were validated. 04:34
Q. Any reason to believe that either 04:34
process was not validated? 04:34

A. No. 04:34
Q. And I believe you testified last time 04:34
that you're not an expert in process validation 04:34
but that you certainly support -- I believe those 04:34
were your words. 04:34
A. Yes. 04:34
Q. From an -- I forget what perspective you 04:34
said. 04:34
A. Cross-functional and analytical 04:34
development testing, troubleshooting. 04:34
Q. That's a fancy way of saying you 04:34
recognize the value and importance of process 04:34
validation. 04:34
A. I absolutely, yeah. 04:34
Q. Okay. 04:34
A. It's a very critical component to the 04:34
whole application development. 04:34
Q. It's kind of a jumping off point for 04:34
everything, isn't it? 04:34
A. Process validation? 04:34
Q. Yes. 04:34
A. Jumping off point? 04:34
Q. Well, with respect actually producing 04:34
and manufacturing a drug product. 04:34
A. Uh-huh. 04:34

Q. You must first develop and validate a process for doing that; correct? 04:34 04:35

A. If you need to develop and validate -- develop a dosage form, a formulation and then to a small scale move it into process validation, that's correct. 04:35 04:35 04:35 04:35

Q. Okay. So once you have a formulation developed -- 04:35 04:35

A. Yes. 04:35

Q. -- the next step is to develop and validate the process; right? 04:35 04:35

A. Scale up first and then validate. 04:35

Q. Okay. So let's make that the not the next immediate step after developing the formulation but two steps later is a process validation. And you cannot go forward with manufacturing any drug product without a validated process; is that correct? 04:35 04:35 04:35 04:35 04:35 04:35

A. That's correct. 04:35

Q. The FDA would not approve either an NDA or an ANDA without demonstration of a validated process; correct? 04:35 04:35 04:35

A. And the demonstration would be for instance in the ANDA III production run. 04:35 04:35

Q. Understood. 04:35

A. That's the output of process validation specifically requiring, you know, a validation, reported development on the application, that isn't necessarily the case. 04:35 04:36 04:36 04:36

Q. In whatever form, you must prove to the FDA -- 04:36 04:36

A. Uh-huh. 04:36

Q. -- that you have developed and validated your process before they will approve your application. 04:36 04:36 04:36

A. Yes. 04:36

Q. Is that correct? 04:36

A. That is correct. 04:36

Q. All right. And a process validation tells you that you have developed a process that allows you to consistently manufacture product within specification; right? 04:36 04:36 04:36 04:36

A. Within the operating parameters of the equipment; correct. 04:36 04:36

Q. Understood. 04:36

A. Uh-huh. 04:36

Q. And as you move forward from your process validation, there are various things that speak to or that confirm the conclusions reached in your process validation study, one of which is 04:36 04:36 04:36 04:36 04:36

manufacturing product within specification over time; correct? 04:37

A. That's one aspect; correct. You also monitor complaints, returns, you know, investigations, that come up during the course of the manufacturing. Lots of different things. 04:37

Q. Understood. 04:37

You continue to monitor the things that might call into question the validation of your process; right? 04:37

A. That's correct. Because in my experience when you go from scale up to manufacturing, invariably as you gain experience with the product there, you'll find things that are potentially difficult. 04:37

Q. And finding things that are potential difficulties, to use your words? 04:37

A. Uh-huh. 04:37

Q. That doesn't mean your process is invalidated. It means you need to investigate and determine whether they require an adjustment of your process; right? 04:37

A. That's open to interpretation. It really is. And the agency, you know, in one circumstance may say your process is out of 04:38

control, it's invalidated, but in another circumstance the same people within the same division may say, you know, it's okay. You need to put in some additional controls. So it's open to interpretation. 04:38

Q. What weight do you give -- in validating as you're undertaking a consulting engagement -- 04:38

A. Uh-huh. 04:38

Q. -- and evaluating whether your client has or is achieving GMP compliance? 04:38

A. Uh-huh. 04:38

Q. What weight do you give to the fact that the client has a validated process followed by years and years and production of literally billions and billions of tablets that were within specification? 04:38

A. I'm sorry. It was a long one, so -- 04:39

MR. ANDERTON: Please read it back. 04:39

(Whereupon, the testimony was read back by the court reporter, as recorded above) 04:39

THE WITNESS: That's obviously an important part of the picture. 04:39

BY MR. ANDERTON: 04:39

Q. Okay. 04:39

A. Supporting process validation and 04:39

showing you're in control. 04:39

Q. Okay. So that is a significant fact 04:39

that -- as you did an evaluation of circumstances 04:39

that met those -- that description, that would be 04:39

one piece of information that you put in, in the 04:39

bucket if you will, suggesting GMP compliance. 04:39

A. One piece. Manufacturing investigations 04:39

would go hand and hand with that in particular. 04:39

Q. Understood. But that fact that I've 04:39

described -- 04:40

A. Uh-huh. 04:40

Q. -- validated process and years of 04:40

in-specification production covering billions of 04:40

tablets, that would go certainly go in the -- 04:40

A. It would. We're assuming that the data 04:40

reporting capture and all that stuff is accurate. 04:40

Q. Understood. 04:40

A. Okay. That's a big assumption because 04:40

it isn't necessarily the case in a lot of 04:40

facilities. 04:40

Q. Okay. 04:40

A. Uh-huh. 04:40

Q. But you would only be able to determine 04:40

whether it was accurate if you looked at the 04:40

data. 04:40

A. You'd have to look at the data and then confirm with individuals that are doing entry into the system, or validation of the system and whatever. 04:40

Q. Understood. 04:40

A. That they would hold up. I'm sorry. No. Would hold up. 04:40

Q. But inherent in what you've just said -- 04:40

A. Uh-huh. 04:40

Q. -- is that you must look at the data in order to challenge it; correct? 04:40

A. The data in a broad sense. 04:40

Q. You used that term, Dr. Bliesner. 04:40

A. Yes, I know. But if we are talking specific process validation, methods validation, data in general because the data can be -- I'm sorry. 04:41

Q. As you used the term? 04:41

A. Yes. 04:41

Q. I was merely trying to ask you questions about how you -- 04:41

A. Okay. 04:41

Q. -- used the term? 04:41

A. Okay. 04:41

Q. Now, you can't use it and then say -- 04:41

A. No. 04:41
Q. -- what the heck are you talking about? 04:41
A. I understand. 04:41
Q. Okay. 04:41
A. I just want to make sure that we're on all on the same page here. It's late in the day and I'm not trying to be evasive. 04:41
Q. I understand but as I understood your answer, if you were going to question or challenge the data -- you said assuming the data. 04:41
A. Are valid. 04:41
Q. Valid. 04:41
A. Your reflection of what's reality. 04:41
Q. Exactly. 04:41
A. Uh-huh. 04:41
Q. The only way you could determine whether the data are valid is to start by looking at the data. There would be other steps you perform, but the first step you'd have to do is look at the data, am I correct? 04:41
A. That's correct. 04:41
Q. Look at page 16 of your report, please. 04:42
A. Yes. 04:42
Q. Give me one second. 04:42
A. Sure. 04:42

Q. Dr. Bliesner, paragraph 39 on page 16. 04:43
Do you see that? 04:43
A. Yes, sir. I do. 04:43
Q. There you discuss investigation into -- 04:43
well, you don't identify the lot number, but -- 04:43
A. No, sir. 04:43
Q. But the lot that had some defectively 04:43
thick tablets discovered during manufacturing. 04:43
And the second to last sentence says: 04:43
"Product is released to market without 04:43
conclusive evidence of what caused the 04:43
double-thick problem on 5 December, 2007." 04:43
That's not accurate is it? 04:43
A. I'd have to go back and pull up the 04:43
reference to be sure. 04:43
Q. Okay. Well you -- 04:43
A. Because it's very -- the investigation, 04:43
if I recall how it's done and how it's written, 04:43
anything like that, it was stuff to pull dates 04:43
together so I can't definitively say that that's 04:43
an incorrect date. 04:43
Q. Well there's -- if you read the 04:43
investigation record, there's plenty of documents 04:43
in the investigation report indicating activities 04:44
occurring. In fact the 100 percent visual 04:44

inspection very clearly didn't occur until January 2008. 04:44

A. Okay. 04:44

Q. So did you just misread that investigation? 04:44

A. Incident report. I'm sorry. What is the question? 04:44

Q. Did you just misread that investigative report? 04:44

A. I don't think so. Like I said, I have to go back and look at it and reconstruct it again to determine if that -- your claim that that's an incorrect date is incorrect. 04:44

Q. You made comment earlier about operators or employees being unable to read or speak English or cannot read English. 04:45

A. Uh-huh. 04:45

Q. What did you do to verify the accuracy of that statement? 04:46

A. I -- if I'm not mistaken, it was in an e-mail and I read the e-mail. 04:46

Q. So you just read the e-mail and that was enough for you? 04:46

A. Yes. 04:46

Q. Okay. So you didn't do anything beyond 04:46

that? 04:46

A. I'm not sure what I could have done 04:46
beyond that, quite honestly. 04:46

Q. Dr. Bliesner, do you understand the 04:46
nature of litigation? You've never been an expert 04:46
witness before. 04:46

A. I have not. 04:46

Q. Do you understand the general nature of 04:46
litigation? 04:46

A. The general nature of litigation? 04:46

Q. Yeah. 04:46

A. How you would define it and how I define 04:46
it, probably different things. 04:46

Q. Well, do you understand that Plaintiffs 04:46
are the ones who bring lawsuits and they make 04:47
allegations against Defendants. They allege that 04:47
certain things happened and in this context -- 04:47
pharmaceutical product liability context -- 04:47
Plaintiffs allege that they were harmed by 04:47
products; right? 04:47

A. That's correct, yes. 04:47

Q. And you understand that the lawyers for 04:47
the Plaintiffs are required to or are attempting 04:47
to prove those allegations. 04:47

A. That's correct, as I understand it. 04:47

Q. Okay. And you understand, then, that the lawyers for the Plaintiffs as part of performing their job are going to go out and find documents that they believe support their position. 04:47

A. I would say that's a fair statement. It would make sense. 04:48

Q. Reasonably self-evident; right? 04:48

A. Yeah, it makes sense. 04:48

Q. Okay. And when you got the documents from Plaintiffs' counsel in this case, I see two primary lists of documents that you got. One is Plaintiffs' exhibits. 04:48

A. Uh-huh. 04:48

Q. And the other Mylan exhibits. 04:48

A. Uh-huh. 04:48

Q. Did it trouble you at all that you were looking only at the documents that Plaintiffs' counsel wanted to you see? 04:48

A. I don't think that's necessarily the way it was. In particular I asked at the start of the project for a list of -- again, go back to my report. I was serving as a consultant, and they asked me to evaluate the status of, you know, the facility in terms of manufacturing restricted to 04:48

Digitek, restricted to Amide, Activis, or whatever, and then they then asked me if there were documents that I thought would be useful for my review so I created the list and gave it to them. 04:49

Q. You did? 04:49

A. Yes. 04:49

Q. Do we have that list? 04:49

A. It was given the last go around. I handed it out, or it was on the disc, one of the two. 04:49

Q. Well, the only thing you gave last go around was Exhibits -- you have them there in front of you, 107, 108? 04:49

A. Uh-huh. It may be on that hard drive. It was provided. 04:49

Q. Okay. And when did you prepare that list that you gave to Plaintiffs? 04:49

A. Very early on in the process. 04:49

Q. Did you get the documents that were on that list? 04:49

A. Not all of then, no. 04:49

Q. Did that trouble you at all? 04:49

A. Trouble is not a word. It was a little frustrating for me. 04:50

Q. What didn't you get? 04:50
A. I would have to look at the list 04:50
specifically. I think like we talked about, I got 04:50
late yesterday evening -- was it process 04:50
validation report, you know, those kinds of 04:50
things. I know there were difficulties with the 04:50
system from my understanding. 04:50
Q. Okay. 04:50
A. In getting documents and they're not all 04:50
loaded up and that kind of stuff. 04:50
Q. Okay. 04:50
A. So. 04:50
Q. Well, so what didn't you get? 04:50
A. I would have to pull up the list. 04:50
Q. But there were things that you asked for 04:50
and didn't get. 04:50
A. That's correct. 04:50
Q. You definitely got all of the 04:50
Plaintiffs' exhibits, though; right? 04:50
A. I -- I can't say whether I got all the 04:50
Plaintiffs' exhibits. 04:50
Q. Well? 04:50
A. If they are all of them, I, then, yes. 04:50
But I don't know if that's all of them. Because 04:50
we -- they created as I understand -- excuse me. 04:50

They created folders that individuals could look at. 04:50

Q. Individual whos? I mean. 04:50

A. People like myself that were reviewing documents. 04:51

Q. Okay. 04:51

A. And those documents that they wished me to review were placed in folders on their electronic system or they delivered them, sent, e-mail -- e-mailed them. 04:51

Q. Okay. 04:51

A. Uh-huh. 04:51

Q. And did you understand as you conducted your paper audit that the Plaintiffs' exhibits were the documents the Plaintiffs' lawyers believed helped them? 04:51

A. Actually I didn't give it any consideration. I was just doing an audit. 04:51

Q. Never occurred to you? 04:51

A. Actually, it did not. 04:51

Q. Well, you weren't necessarily doing an audit. You were looking at the documents they selected to give you. 04:51

A. I don't think that's a -- that's fair statement. 04:51

Q. Is it not fair wholly or is it not fair just partially. I mean you got all the documents they wanted you to have but did not get the documents, all of the documents you asked for. 04:51

A. That's a true statement. 04:51

Q. Okay. 04:51

A. And why that happened, I'm not sure. Other than it was -- 04:52

Q. Got a guess? 04:52

A. No. Remember rule number one, don't guess. 04:52

Q. I understand. I understand. 04:52

A. And that's what so much of this has been today is that I'm trying to make sure that I'm not guessing. 04:52

Q. I don't want you to guess. 04:52

A. Yes. 04:52

Q. But you're a sharp guy. I'm sure you can figure out why it is that you got what they wanted you to have but didn't get everything you asked for. 04:52

A. I wouldn't comment on that. 04:52

Q. Does it trouble you at all Dr. Bliesner that nobody has produced a single double-thick tablet from the market from the recalled batches? 04:53

A. Trouble? 04:53

Q. You're a GMP compliance expert. You've 04:53

conducted $140,000's worth of analysis here, 04:54

reaching the conclusion that you think adulterated 04:54

product reached the market, yet no one has 04:54

produced a double-thick tablet from the recalled 04:54

batches in almost three years since the recall. 04:54

A. They have not. That's a fact. 04:54

Q. That's a fact? 04:54

A. Okay. I take you at your word. 04:54

Q. That's a fact. Does that trouble you? 04:54

A. Trouble is not a word that I would use; 04:54

okay? 04:54

Q. Does it have any impact on the way you 04:54

think about your engagement or about on the 04:54

conclusions that you you've reached? 04:54

A. No, not necessarily. Even though again 04:54

we've established I'm not a recall expert. 04:54

Recalls are not a science -- let's put it that 04:54

way -- and we've already established that there 04:54

are a large number. 04:55

Q. 680 million. 04:55

A. Billion I think is what Mr. Moriarty 04:55

said last go around. 04:55

Q. Subject to the recall, 680 million. In 04:55

fact Plaintiff told you that in your meeting before your deposition. 04:55

A. Yes, sir. That -- 04:55

Q. And -- 04:55

A. -- a small number of a large number is still substantial in my mind. 04:55

Q. Zero is not substantial, is it? 04:55

A. Just because you haven't seen anything doesn't mean it's not there, especially when you look at the lack of controls within that facility. 04:55

Q. You're relying on inferences again; right? 04:55

A. I don't think it's inferences. 04:55

Q. You don't have any direct proof so it must be an inference; right? 04:55

A. I don't think an inference. It's a mass of data. I think that the thing that troubles me more than anything -- I'm sorry. I'm done. 04:56

Q. It's a mass of data that create an inference. 04:56

MR. KERENSKY: There you go again, Mike. 04:56

MR. ANDERTON: Mike, he stopped his answer and said I'm done. 04:56

MR. KERENSKY: He took a breath. 04:56

MR. ANDERTON: He said -- 04:56

MR. KERENSKY: And you jumped on him. Let him finish.

MR. ANDERTON: Mike, he said I'm done.

MR KERENSKY: Read it back. If you are right, I'll take it back.

(Whereupon, the testimony was read back by the court reporter, as recorded above)

Q. Are you done, Dr. Bliesner?

A. On which point here?

Q. Exactly.

MR. KERENSKY: Let's read back what he was saying when you jumped on his sentence there.

MR. ANDERTON: And I think the record clearly showed earlier that he interrupted me. I let that go. Go ahead, Phil.

MR. KERENSKY: I think his last word was "and."

MR. ANDERTON: No, it wasn't.

MR. KERENSKY: What was the last word before you said no, no. I couldn't quite hear Phil. He was fairly far away.

MR. ANDERTON: The thing that tells me more than anything.

MR. KERENSKY: You don't end a sentence

in anything. 04:57

MR. ANDERTON: Mike, the problem is, he 04:57

answered my question. He recognized -- 04:57

MR. KERENSKY: There's just disagreement. 04:57

MR. ANDERTON: He recognized -- Mike, he 04:57

recognized and stopped himself when he was 04:57

answering a question that hadn't been asked. 04:57

He did it. 04:57

MR. KERENSKY: Well, I don't how he could 04:57

be doing both, Mike. He was still talking and 04:57

you interrupted him. That's all there is to 04:57

it. 04:57

MR. ANDERTON: I didn't interrupt him, 04:57

Mike. Now, I really don't appreciate this -- 04:57

I mean you are telling him what to do, Mike. 04:57

It's inappropriate. 04:57

MR. KERENSKY: I'm telling you what to 04:57

do. Don't interrupt him. 04:58

MR. ANDERTON: Dr. Bliesner, are you 04:58

done? 04:58

MR. KERENSKY: Read that whole answer 04:58

back before Mike started talking again and 04:58

then ask him that question and we'll move on. 04:58

MR. ANDERTON: I asked him the question. 04:58

He stopped himself, Mike. You're not here. 04:58

He put his hands up and said "I'm sorry." And he stopped and said --

MR. KERENSKY: And you started to interrupt him.

MR. ANDERTON: Not true. Dr. Bliesner, do you have anything to add to that answer?

MR. KERENSKY: If you need to hear it read back to you, Dr. Bliesner, you may ask for that.

THE WITNESS: Read it back one more time, please.

(Whereupon, the testimony was read back by the court reporter, as recorded above)

THE WITNESS: Was the fact that nobody ever tested double-thick tablets they found in the facility. That's what I find troubling.

BY MR. ANDERTON:

Q. Okay. But is that more --

MR. KERENSKY: Make your objection, Mike.

BY MR. ANDERTON:

Q. Is that more troubling to you, Dr. Bliesner, than the fact that out of 680 million tablets, in three years nobody has presented a single double-thick tablet?

A. Absolutely because not testing on a

product that's clearly failed and identified had failed is -- it really raises eyebrows. All kinds of questions come up. Why didn't they? Is somebody hiding something? Have found things before? Are they dumping it? These are just questions that come to mind. I'm not suggesting --

Q. All of --

A. -- all of these things. Just a whole plethora of questions come into play when you don't see -- it's happened several times as we both recognize.

Q. And the way to answer those questions would be to take them and dive into the manufacturing and production records for that product.

A. No, that's not true.

Q. Or for any other product.

A. That's not true. They didn't collect the samples and test them.

Q. The way --

A. In my experience -- in my experience with respect to batch records, okay, personal experience, recent personal experience, batch records don't necessarily reflect reality. I've

had a client in the last year that manufactures product and doesn't even look at the batch record because it isn't written where you can follow it. They just go out there and wing it on the floor. So just because you got a batch record doesn't mean that that's gospel what's happening on the floor. That's my personal experience. 05:00

Q. Did you throw your medicine from that manufacturer away? They're not following their batch records. Did you go run up to your medicine cabinet and throw that away? 05:00

A. It's not appropriate. 05:00

Q. What do you mean it's not appropriate? 05:01

A. Because it's not a solid oral dosage for me. 05:01

Q. Dr. Bliesner, last time you talked about, you gave some testimony about conversation you had with your doctor regarding this subject, the subject of this litigation. And I wasn't satisfied that we established whether the conversation was in fact protected by a physician-patient privilege. So I am going to ask some questions to develop the details surrounding that conversation that will tell us that. 05:01

A. And I'm not going to answer those 05:01

questions.
Q. You don't have right to refuse to answer that unless you -- unless it is truly privileged. Do you understand that?
A. I believe it's truly privileged between my doctor. Because I specifically asked that because he asked me.
Q. Were you seeking medical advice when you asked him these questions?
A. I was in for an appointment yes.
Q. Were you seeking medical advice when you asked him questions about Digoxin?
A. When I asked him questions about it? I didn't ask him questions. He volunteered.
Q. How did he come to volunteer?
A. I'm not comfortable talking about this.
Q. I'm not asking for the substance
A. I'm not comfortable talking about it.
Q. You don't have a choice.
MR. KERENSKY. Mike, maybe I can settle this. No one is going to ask this witness to tell any jury what his doctor said about Digitek. I will stipulate to that right now.
MR. ANDERTON: Well, we're going to ask this witness what his doctor told him so we

know whether it formed part of the basis for his expert opinion in this case. 05:02

THE WITNESS: It was after the fact. I will tell you that. 05:02

BY MR. ANDERTON: 05:02

Q. You are still subject to testifying, Dr. Bliesner. 05:02

MR. KERENSKY: You have a right to protect your conversations between you and your doctor. And you've got two countervailing opinions from two lawyers, neither of which represent you. You got to make the call, doctor. 05:02

BY MR. ANDERTON: 05:03

Q. Dr. Bliesner, you know what you're doing here. You're setting yourself up to be brought back for another session of deposition. 05:03

A. So be it. I am not comfortable sharing that information with you. 05:03

Q. I'm allowed to ask the parameters of the conversation. I'm not asking for the substance. I'm allowed to ask the details of the conversations that surround the conversation so that I can evaluate whether I think it's a privileged communication or not. 05:03